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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/762,133

01/20/2004

Stephen D. Russell

79934

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32697 7590 10/30/2007
OFFICE OF PATENT COUNSEL
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EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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10/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/762,133

Applicant(s)

RUSSELL ET AL.

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 August 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,5-7,9,10,13 and 15-45 is/are pending in the application.
4a) Of the above claim(s) 17-27 is/are withdrawn from consideration.
- 5) Claim(s) 13,15,16,44 and 45 is/are allowed.
- 6) Claim(s) 1,5-7,9,10,28,30 and 37-43 is/are rejected.
- 7) Claim(s) 29 and 31-36 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
- Certified copies of the priority documents have been received.
 - Certified copies of the priority documents have been received in Application No. _____.
 - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

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Claims 17-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/16/2006.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has not disclosed how to calculate or otherwise determine the triage index or the shock assessment index. Accordingly, the claims lack enablement. No art is being applied to these claims, but the art rejection will be revisited upon resolution of the above issue.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 9, and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koning et al 4534825 in view of Abreu (PGPUB 2002/0049389). Referring to claim 1 Koning et al. teach a probe comprising a housing, which includes the catheter on the exterior and the substrate on the interior, where the housing has an aperture, an ISFET attached to the housing (column 2 lines 57-63), wherein the ISFET has a gate located proximate to the aperture (column 3 line 64-column 4 line 6), a reference electrode attached to the housing proximate to the aperture (column 3 lines 33- 44). The housing is not hermetically sealed. Abreu teaches a sensor, which comprises an ISFET and a housing, which seals the housing to prevent fluids from disrupting the electrical circuits and the sensor. Since both sensors use the same ISFET technology and are used in wet locations, they are from analogous arts. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the probe of Koning et al. to include a hermetically sealed encapsulant similar to that of Abreu in order to prevent fluid invasion causing problems in the electronics. With respect to claim 9, Abreu teaches the use of a battery coupled to the ISFET (page 15 paragraph 0158). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the probe of Koning et al. to include a battery similar to that of Abreu in order to provide a power source. Claims 37 and 38 are rejected in that there is a control module in the monitoring device, which can be held by hand. Claim 39 is rejected in that the examiner takes official notice that wireless communication has become well known in the medical arts to prevent infection and to allow mobility for the patient. Hence, it

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would have been obvious to modify the combination above to use wireless communication, as it is merely the substitution of one known communication means for another. Claim 40 is rejected in that the processor is configured to perform statistical analysis.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koning et al. '825 in view of Abreu, as applied to claims 1, 9, and 37-40 above, further in view of Tomita et al. (U.S. Patent No. 5814280). Referring to claim 5 Koning et al. teach all of the limitations of the claim but fail to teach that the ISFET and reference electrode are integrally formed on the substrate, wherein the ISFET and reference electrode are monolithically integrated and the ISFET and the microelectrode are located on a portion of the substrate that includes the aperture. Tomita et al. teach a substrate including an ISFET and a reference electrode above the ISFET (column 4 lines 29-45). It would have been obvious to have the combination located on a portion of the substrate that includes the aperture in order to introduce the substance being measured to the ISFET to be able to measure the amount of the substance. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the probe of Koning et al. to include a substrate similar to that of Tomita et al. in order to make the unit more economical to manufacture (Tomita et al. column 4 lines 52-60). Referring to claim 6, Tomita et al. teach that associated circuitry can be integrated with the ISFET and the reference electrode (column 4 lines 45-51). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the probe of Koning et al. to integrate the associated circuitry similar to that of Tomita et al. in order to make the

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unit more economical to manufacture. Referring to claim 7 Tomita et al. teach the integrated circuitry includes a temperature sensing diode (column 4 lines 36-37). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the probe of the combination et al. to include a temperature sensing diode similar to that of Tomita et al in order to compensate for drift related to temperature change (Tomita et al. column 4 lines 37-39).

Claim 10 is rejected under 35 U.S.'C. 103(a) as being unpatentable over Koning et al.'825 in view of Abreu, as applied to claims 1, 9, and 37-40 above, further in view of Ishikawa et al. (US Patent No. 6447448). Referring to claim 10, Ishikawa et al. teach an antenna and capacitor system in which the antenna is coupled to the capacitor and the capacitor is coupled to the ISFET wherein the capacitor is configured to store electromagnetic energy received by the antenna (column 13 lines 33-53). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the probe of combination above et al. to include the antenna system similar to that of Ishikawa et al. in order to create a system in which no battery is required.

Claim 28 is rejected under 35 U.S.'C. 103(a) as being unpatentable over Koning et al.'825 in view of Abreu, as applied to claims 1, 9, and 37-40 above, further in view of Otten et al 4706678. Koning teaches it is for measuring chemical parameters of the blood. Otten teaches that it is known to measure pH of the blood. Hence, it would have been obvious to modify Koning to measure pH, as it is merely the use of the device for a well known purpose in the art.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koning et al. '825 in view of Abreu and Tomita et al, as applied to claims 5-7 above, further in view of Otten et al 4706678. Koning teaches it is for measuring chemical parameters of the blood. Otten teaches that it is known to measure pH of the blood. Hence, it would have been obvious to modify Koning to measure pH, as it is merely the use of the device for a well known purpose in the art.

Allowable Subject Matter

Claims 13, 15, 16, 44, and 45 are allowed. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fail to teach or fairly suggest a microsensor system comprising a cantilever arm attached to an actuator and a microprobe comprising an ISFET and a reference electrode.

Claims 29 and 31-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 29 and 31-36 define over the art in that none of the art has 2 ISFETs, with both having a gate proximate the aperture in the housing, as claimed.

Applicant's arguments filed 8/22/07 have been fully considered but they are not persuasive.

Applicant has asserted that modifying Koning to use a sealing encapsulant would destroy the purpose of Koning, as no calibration fluid could be administered. The

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examiner disagrees, noting that the combination does not seal the entire catheter, just the housing of the ISFET.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser jr./
Robert L. Nasser
Primary Examiner
Art Unit 3735

RLN
October 29, 2007